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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/05/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,143

Applicant(s)

Nair et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 1, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 15-18, 27-30, and 34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 15-18, 27-30, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1, 3-6, 15-18, 27-30 and 34 remain pending and were presented for examination on the merits.

The Finality of the Office Action set forth on 10/30/11 (Paper No. 10) is hereby withdrawn in light of new grounds for rejection, *infra*. The Amendment After Final Rejection filed 1/28/02 was entered. Arguments presented in the After Final Amendment as well as arguments found in the Appeal Brief filed 5/1/02 pertaining solely to previous rejections are moot in light of this new rejection, however, relevant arguments which could pertain to the new grounds of rejection and directed toward remaining rejections were fully considered and discussed *infra*.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 3-6, 15-18, 27-30 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the specification is enabling for a "mixture of cyanidin and an anthocyanin" and point out several places in the Specification which they deem provide support for said language (p.9- Appeal Brief). However, the specific composition, as recited in the claims; i.e., 'cyanidin and an anthocyanin' is not found within the examples provided by Applicants. Canceled claim 21 recited a method for inhibiting inflammation, but did not mention inhibition of the enzymes as in the Instant claims. Further, Claim 21 stated '..comprises administering anthocyanin including cyanidin.' This statement is confusing, and the Examiner cannot conclude from this limitation that it would necessarily mean a composition comprising a 'cyanidin and an anthocyanin.' Thus, the Examiner cannot extrapolate the language which has been rendered New Matter from the examples set forth by the Applicants.

Again, it is deemed that the Disclosure, as filed, does not contain reference to such a specific composition which includes cyanidin and an anthocyanin, and thus lacks a written description of the claimed invention and constitutes New Matter.

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Claims 1, 3-6, and 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lietti et al. (GB 1,598,294) in view of Wurm et al. (1982).

Applicant's arguments were fully considered, but not found persuasive.

Applicant's principal argument resides in the fact that Wurm et al. did not disclose the structure of anthocyanins. Upon further evaluation of the structure on p.2062 of Wurm et al., it is agreed that the structure does not describe cyanidin. However, Wurm et al. did disclose, as discussed in previous Office Actions, that "All flavonoids, regardless of the stereochemistry and degree of oxidation of their heterocyclic rings, are prostaglandin synthetase (PGS) inhibitors if at least one ring has a pyrocatechol structure" (pp. 6, English Translation). Because anthocyanins are flavanoids with pyrocatechol structures, one of ordinary skill in the art would have had a reasonable expectation that anthocyanins would have had some effect on inflammation.

The combination of two constituents which were known to inhibit inflammation is deemed to be obvious, especially in light of *In re Sussman* 1943 C.D. 518 (please see previous Office Actions). Secondly, Lietti et al. clearly teach that anthocyanins are hydrolyzed to cyanidin (p.1, lines 27-28, in addition to the same teaching in the Instant Specification). Thus, that *in-vivo*, anthocyanins are all converted (hydrolyzed) to the non-glycosylated anthocyanidins before entry into the intestinal tract. Consequently,

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one of ordinary skill in the art would have recognized then that cyanidin and anthocyanins, the glycosidic forms of cyanidin, would have been virtual pharmaceutical equivalents since anthocyanins essentially degrade in the body to cyanidin.

Claims 1, 3-6, 15-18, 27-30 and 34 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Lietti et al. (GB 1,598,294) in view of Wurm et al. (1982) and further in view of Heckert et al. (US 5,516,535). Claims 15-18 are drawn to wherein the combination of cyanidin and an anthocyanin are admixed with berry pulp.

The teachings of Lietti et al. And Wurm et al. were discussed *supra*, as well as in previous Office Actions. Neither reference mentioned wherein the combination of anthocyanin and cyanidin were admixed with berry pulp in specific ratios.

It was routine in the art to combine extracts from fruit back into the endogenous juice/pulp of the fruit to utilize as a carrier. Heckert et al. (US 5,516,535) for example, disclosed a beverage composition which comprised both Vitamin C and orange pulp (Vitamin C is extracted from orange) (col.6, Example II). One of ordinary skill in the art would have been motivated to add the anthocyanin/cyanidin mixture back into dried berry pulp or fresh berry pulp because it was routine in the art to mix extracts obtained from fruit back into the pulp as disclosed by Heckert et al., in order to create a nutritional composition attractive to the consumer.

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Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to add the final anthocyanin mixture back into a food grade carrier in ratios anywhere from .1 to 100 (anthocyanins:carrier) or 100 to .1 (anthocyanins:carrier) in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

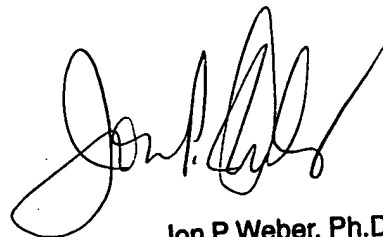
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a large, stylized initial 'J' and 'W'.

**Jon P. Weber, Ph.D.
Primary Examiner**